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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BIONPHARMA INC., Plaintiff, v. CORERX, INC., Defendant.	Case No. 1:21-cv-10656

DECLARATION OF AJAY DAMANI IN OPPOSITION TO PLAINTIFF BIONPHARMA, INC.'S MOTION FOR PRELIMINARY INJUNCTION

I, Ajay Damani, declare as follows:

1. I am the President and Chief Executive Officer ("CEO") of CoreRx, Inc., a position I have held since October of 2021. I have over 10 years of experience in the pharmaceutical contract development and manufacturing industry. This experience spans branded, generic, specialty, and over-the-counter medicines and across pharmaceutical product development, manufacturing, and marketing.

2. My responsibilities as the CEO of CoreRx include ensuring the financial health of the business, overseeing approximately 200 employees, including the executive leadership team, and setting and implementing business strategy.

3. I submit this Declaration in support of CoreRx's Opposition to Plaintiff Bionpharma Inc.'s ("Bionpharma") Motion for Preliminary Injunction.

4. I have personal knowledge of the following facts and, if called to testify, I could and would testify competently to the matters stated herein.

A. The CoreRx Business and Ownership Structure

5. CoreRx is a pharmaceutical Contract Development Manufacturing Organization founded in 2006 with sites in Clearwater, Florida and San Rafael, California. On behalf of its pharmaceutical customers, CoreRx develops and manufactures clinical trial and commercial drug products. CoreRx's business is focused mainly on oral solids and liquids, and product sold and used primarily in the United States market. In a given year, CoreRx has over eighty development programs in progress that are funded exclusively by CoreRx customers.

6. A majority of the stock in CoreRx was acquired by NovaQuest Private Equity ("NovaQuest") in January, 2021. NovaQuest also owns a controlling interest in Azurity Pharmaceuticals, Inc. ("Azurity"), the pharmaceutical company which manufactures and sells Epaned®, the reference listed drug of Bionpharma's Abbreviated New Drug Application for its enalapril maleate oral solution product, the product at issue in this litigation (the "Product").

7. It is not uncommon in the pharmaceutical industry for a private equity fund, such as NovaQuest, to invest in multiple pharmaceutical companies and service providers to the industry. Such companies, as here, frequently act totally independently from one and other and,

given the nature of the industry, experience business disputes from time to time which result in litigation.

8. A similar example of the interconnectedness of the pharmaceutical industry is the common investment in the two parties to the present dispute. Signet, LLC, the private equity firm that owns a majority interest in Bionpharma, maintains an interest in CoreRx of approximately $17 million. Prior to the acquisition of CoreRx by NovaQuest, Bionpharma's CEO and CFO were members of the CoreRx board of directors. Upon information and my belief, these individuals influenced the pricing of the products that CoreRx developed and manufactured for Bionpharma to the financial benefit of Bionpharma.

9. Bionpharma's suggestion that CoreRx and Azurity are somehow working in collusion in this matter so as to advance each other's interests is false. To the contrary, I personally reached out to certain NovaQuest Board members who also sat on the Azurity Board, seeking to discuss the lawsuits brought by Azurity against CoreRx. My efforts were rebuffed and I was told that NovaQuest would take no position one way or another with regard to any dispute and that both parties should proceed in what they deemed to be their own best interests.

B. <u>The Manufacturing Supply Agreement</u>

10. CoreRx began doing business with Bionpharma in approximately 2017. Over the course of the past 4 years, CoreRx has developed and manufactured a portfolio of generic oral liquid pharmaceutical products, for Bionpharma, which Bionpharma has proceeded to market and sell to the public.

11. In November, 2020, CoreRx and Bionpharma entered into that Master Manufacturing Supply Agreement (the "Contract") whereby, subject to certain express limitations, CoreRx agreed to manufacture certain agreed upon pharmaceutical products for

Bionpharma.[1] Upon information and belief, Bionpharma was the sole drafter of the Contract and inserted the alternate dispute resolution provision in question in this action. CoreRx signed the Contract as drafted by Bionpharma.

12. In August 2021, Bionpharma launched its enalapril maleate oral solution product, a generic version of Azurity's Epaned®. Bionpharma thereafter placed its first order for the Product under the Contract and CoreRx faithfully manufactured and supplied the Product pursuant to every purchase order received, through the end of November, 2021. CoreRx did not cease manufacture until its settlement with Azurity, as described below.

13. CoreRx manufactured and supplied 8 lots of the Product to Bionpharma to fill the firm orders pursuant to the Contract during that time period.

C. <u>The Azurity Patents and Patent Infringement Litigation</u>

14. Azurity brought two federal lawsuits against CoreRx after the date of the Contract and subsequent to orders for the Product.[2] Azurity alleged that CoreRx's manufacture and supply of the Product for Bionpharma constituted patent infringement of certain patents which had recently been issued in favor of Azurity.

15. Specifically, two separate patents had been issued by the United States Patent and Trademark Office ("USPTO") to Azurity, U.S. Pat. No. 11,040,023 issued on June 22, 2021 and U.S. Pat. No. 11,141,405 issued on October 12, 2021 (together, the "Azurity Patents").

16. CoreRx settled both patent infringement lawsuits with Azurity in November, 2021 and the two cases were subsequently dismissed by Azurity, without prejudice. As part of the

[1] A true and correct copy of the Contract is filed under seal with this Court, annexed to the Declaration of Venkat Krishnan ("Krishnan Dec.") as **Exhibit F** (ECF Doc No. 10-1).
[2] *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, United States District Court for the Middle District of Florida, No. 8:21-cv-02515-TPB-SPF and *Azurity Pharmaceuticals, Inc. v. CoreRx, Inc.*, United States District Court for the District of Delaware, No. 1:21-cv-01522.

parties' settlement, CoreRx agreed to cease making, using, selling, importing, or offering to sell the Product. Importantly, CoreRx was not compensated for entering into the settlement.

17. It is my understanding that patents issued by the USPTO are deemed to be valid until and unless they are determined to be invalid by a court of competent jurisdiction. To date, no court has held that the Azurity Patents are invalid.

18. CoreRx reasonably believes that Azurity would reinstate the lawsuits and/or take other legal action against CoreRx if CoreRx were to once again manufacture and supply the Product to Bionpharma, exposing CoreRx to the specter of catastrophic monetary damages, including treble damages. *See* Hofmann Decl., ¶ 44.

19. On or about December 1, 2021, CoreRx ceased production at the manufacturing lines previously devoted to the manufacture of the Product. These manufacturing lines were reconfigured and transitioned for the manufacture of other products which CoreRx is currently manufacturing for Bionpharma.

D. <u>The Contract Renegotiation Between CoreRx and Bionpharma for the Entire Product Line</u>

20. The Contract contemplated an annual renegotiation of the price that Bionpharma pays CoreRx for the entire product line, including the Product at issue here. *See* Krishnan Dec., Exhibit F, Contract, Section 6.2 (the "Transfer Price" was to be established by mutual agreement of the parties on an annual basis.).

21. In accord with this provision, CoreRx advised Bionpharma by letter dated November 19, 2021 that there would be price increases for a number of products, including the Product.[3]

[3] A true and correct of the November 19, 2021 letter is filed under seal with this Court, annexed to the Krishnan Dec. as **Exhibit I** (ECF No. 10-4).

22. By letter dated November 23, 2021, Bionpharma advised CoreRx that it would not agree to any of the suggested pricing.[4] Bionpharma did however, inquire as to the reason for the cost increases. CoreRx subsequently provided Bionpharma with an analysis demonstrating CoreRx's rationale for the price increases.

23. The price increases were requested across the Bionpharma portfolio and were not specific to the Product. The price increases were also requested prior to the settlement with Azurity.

24. The parties have not reached mutual agreement on any of the pricing set forth in CoreRx's November 23, 2021 letter. Because the parties have failed to reach a mutual agreement with respect to pricing, it is CoreRx's position that the parties have not reached an agreement and CoreRx will manufacture products for Bionpharma on a purchase order by purchase order basis.

E. <u>The Supply Interruption and CoreRx's Decision to Terminate the Contract for the Product</u>

25. The litigation brought by Azurity placed CoreRx in an untenable position. CoreRx could not manufacture and supply Bionpharma with the Product without exposing itself to certain patent infringement litigation and the significant monetary damages flowing therefrom. This created a supply interruption in the manufacture and supply of the Product. But for this threat of continued patent infringement litigation and the attendant financial exposure, CoreRx would have continued to manufacture and supply the Product to Bionpharma. Indeed, CoreRx's inability to produce the Product for Bionpharma is impacting CoreRx's revenue negatively.

[4] A true and correct copy of the November 23, 2021 letter is filed under seal with this Court, annexed to the Krishnan Dec. as **Exhibit J** (ECF No. 10-5).

26. The Contract anticipates that a supply interruption of any one of the products subject to the Contract may occur from time to time. Specifically, Section 5.11 provides for an agreed upon procedure for addressing such supply interruptions.

27. In accord with the Contract, CoreRx notified Bionpharma on November 30, 2021 that it was unable to further manufacture and supply the Product as a result of a supply interruption.[5]

28. Bionpharma responded by letter dated November 30, 2021 whereby, among other things, Bionpharma invoked Section 16.7 of the Contract that it drafted (entitled "Dispute Resolution") and, as contemplated thereunder, demanded a meeting between senior executives.

29. A teleconference took place on December 7, 2021. I participated on behalf of CoreRx and Mr. Venkat Krishnan participated on behalf of Bionpharma. Counsel also participated.

30. The conference call lasted approximately 30 minutes. CoreRx explained that a supply interruption had occurred and that CoreRx was in the process of actively identifying potential alternative suppliers of the Product as anticipated by Section 5.11 of the Contract. I assured Bionpharma that CoreRx would continue to diligently seek an alternative supply and work closely with Bionpharma in doing so. CoreRx did not reveal the precise nature of the supply interruption due to confidentiality concerns that I maintained at the time. Importantly, Bionpharma did not comply with the remainder of the Dispute Resolution requirements set forth in the Contract before filing this action.

[5] A true and correct copy of the November 30, 2021 letter is filed under seal with this Court, annexed to the Krishnan Dec. as **Exhibit K** (ECF No. 10-6).

31. CoreRx has diligently worked to find an alternative supplier for Bionpharma and has met all requests by Bionpharma in good faith. Among other things, CoreRx has contacted and engaged in discussion with not less than four separate companies regarding their ability to supply Bionpharma with the Product. CoreRx introduced Bionpharma to the interested companies so that Bionpharma could evaluate and proceed with one or more of the entities of their choosing. In addition, at the request of Bionpharma, CoreRx has provided information and Product material to other potential suppliers identified by Bionpharma to enable such manufacturers to act as alternate manufacturers. Further, CoreRx has promptly provided information and Product materials to the potential suppliers per Biopharma's request. CoreRx intends to continue these efforts until an alternative supply is identified.

32. In the meanwhile, CoreRx continues to timely manufacture and supply all of the other products subject to the Contract and the remaining capacity left by our inability to supply the Product remains idle.

33. CoreRx is also aware that Bionpharma is currently in litigation involving the Azurity Patents. For example, I have been informed that the patent infringement suit involving U.S. Patent No. 11,040,023 was originally asserted against Bionpharma in the District of New Jersey under C.A. No. 21-12870. However, this litigation has since been transferred to the District of Delaware under C.A. No. 1-21-cv-01286. I have also been informed that U.S. Patent No. 11,141,405 was also been asserted against Bionpharma in the District of Delaware in a separate litigation under 1-21-cv-01455 (DDE). CoreRx anticipates that it would reinstate the manufacture and supply of the Product for Bionpharma should the Azurity Patents be found to be invalid, thereby freeing CoreRx to proceed without the current liability.

F. The Consequences of Continued Manufacture and Supply of the Product

34. CoreRx cannot absorb the potential monetary damages that could result from the Azurity litigation. *See* Hofmann Decl., ¶ 44.

35. CoreRx's business would be destroyed if it is exposed to a liability of such a magnitude. *Id.* Indeed, bankruptcy and closure would be inevitable.

36. Bionpharma has offered to indemnify CoreRx for any damages which CoreRx may incur in litigation with Azurity, provided CoreRx continues to manufacture and supply the Product. However, given the magnitude of CoreRx's potential liability, and based upon my knowledge of the industry, it is my opinion that Bionpharma does not possesses the financial wherewithal to meaningfully indemnify CoreRx herein. As a result, it would be financially irresponsible to face this potential liability with only a Bionpharma indemnification to backstop CoreRx from financial ruin.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated: December 29, 2021

Ajay Damani